NIH Guide: TRANSLATING RESEARCH INTO PRACTICE - JOINT PROGRAM ANNOUNCEMENTTRANSLATING RESEARCH INTO PRACTICE - JOINT PROGRAM ANNOUNCEMENT

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PARTICIPATING INSTITUTES AND CENTERS (ICs):

Department of Veterans Affairs, Health Services Research and Development Service
Agency for Healthcare Research and Quality, AHRQ (http://www.ahrq.gov)

THIS PA CONTAINS THE FOLLOWING INFORMATION:

PURPOSE OF THE PA

This Translating Research into Practice (TRIP) Program Announcement (PA) is a collaborative effort between the Health Services Research and Development Service (HSR&D) within the Department of Veterans Affairs (VA)and the Agency for Healthcare Research and Quality (AHRQ). Applicants are invited to conduct innovative and rigorous research and evaluation projects related to the translation of research findings into measurable improvements in quality, patient safety, health care outcomes and cost, use, and access. An explicit focus on testing effective strategies for translating research into practice has been a priority for the PA sponsors for the past several years. While there are promising initiatives and projects in progress, this PA underscores the need for research that can bridge the chasm between promising prototypes (e.g., approaches for treating a specific disease in a particular setting or

work system changes that improve quality or efficiency in a particular setting) and generalizable knowledge that can be used in multiple settings and lead to systematic improvement on a large scale. For the purpose of this PA, research findings may be translated into evidence-based clinical or organizational, structural, and system interventions that then can be assessed for their ability to measure change in or improve access to health care, patient safety, the quality and/or cost-effectiveness of health care delivery, and health care outcomes.

This PA represents AHRQ's, and VA's continued interest in translating research evidence into practice and their desire to build on existing research in this field. This collaborative effort will provide an opportunity to compare and contrast the challenges of making use of research findings at the public policy level, within and across different systems of care, and contribute to the goal of identifying effective and efficient interventions that have the potential to be used to improve clinical practice, enhance patient safety, and sustain practitioner behavior change across populations, multiple health conditions, and health care systems.

Two specific priorities under this PA are to: 1) compare the use of interventions to translate research into practice across different health care systems (e.g., comparison of translation in a VA facility and in a non-VA facility using the same design, methods, measures and patient population) and 2) measure the impact of translation activities (including the testing of interventions that foster measurable and sustainable quality and patient safety improvement or consistent quality and patient safety at a lower cost).

The inclusion of a VA site is not a requirement of the PA. If a VA setting is included, the PA does provide the opportunity for investigators to focus on common translation problems within public and private-sector health care delivery organizations/systems and the VA health care system. The investigator must meet the eligibility requirements of VA to be eligible for VA funding of the VA site (see VA HSR&D Eligibility Requirements).

Projects that focus on identified disparities in health status, health care quality, and access experienced by certain groups, notably racial and ethnic minorities as well as those with low-income, are encouraged. The PA sponsors also encourage projects that focus on women, and the elderly; individuals with special healthcare needs, including persons with disabilities, and those who need chronic care and end of life health care; and individuals living in inner-city, rural, and frontier areas. AHRQ encourages investigators to consider inclusion of children in study populations, as appropriate. The PA sponsors encourage innovative studies that have the potential for broad impact, involving multi-disciplinary and multi-facility patient-centered approaches, to the translation of evidence into practice. The study of patients with specific conditions, particularly one or more chronic illnesses

across their continuum of care, is also encouraged.

The National Institutes of Health: National Institute of Mental Health (NIMH), National Cancer Institute (NCI), and National Institute of Alcohol Abuse and Alcoholism (NIAAA) are interested in co-sponsorship of applications supported under this PA. For inquiries see key staff listed under "WHERE TO SEND INQUIRIES."

RESEARCH OBJECTIVES

Background

This announcement is intended to solicit applications that jointly support AHRQ and VA HSR&D translation of research into practice activities and to contribute to the goals set forth in the recent IOM report, Crossing the Quality Chasm, March 2001. AHRQ and VA have supported important work on translation of research findings into practice. Information describing currently funded AHRQ projects is available upon request from AHRQ. Information describing translation projects currently funded by VA, is available from VA. (see WHERE TO SEND INQUIRIES).

AHRQ has issued a series of RFAs that support research on the translation of research findings/implementation of research findings into sustainable improvements in clinical practice and patient outcomes: the Translating Research Into Practice (TRIP) RFA (http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-99-003.html), published January 8, 1999; the Assessment of Quality Improvement Strategies in Health Care RFA (http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-99-002.html), published January 22, 1999; the Systems-Related Best Practices to Improve Patient Safety RFA (http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-00-007.html), published December 16, 1999 and the Translating Research into Practice II RFA (http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-00-008.html), published December 16, 1999. This PA extends AHRQ=s interest in these areas and builds on the type of research funded under these RFAs.

AHRQ program announcements and grants policy statements (listed above) are available through the AHRQ Web site http://www.AHRQ.gov (Funding Opportunities) and from the AHRQ Publications Clearinghouse (see Inquires).

The TRIP RFA funded research that generated new knowledge about approaches that are effective and cost-effective in promoting the use of research evidence in clinical settings and lead to improved health care practice and sustained practitioner behavior change. The Assessment of Quality Improvement Strategies in Health Care RFA funded projects that are evaluating strategies in widespread use by organized quality improvement systems for improving

health care quality. The Systems-Related Best Practices to Improve Patient Safety RFA applications are testing the effectiveness of the transfer and application of best practices to improve patient safety through the reduction of preventable system-related medical errors. The TRIP II RFA funded projects are evaluating strategies for translating research into practice through the development of partnerships between researchers and health care systems and organizations (e.g., purchaser groups, integrated health service delivery systems, academic health systems, managed care programs including HMOs, practice networks, and worksite clinics). In addition to identifying effective and efficient strategies to implement research evidence to achieve measurable and sustainable improvements in health care, the goal of the TRIP II RFA was to develop and identify sustainable and replicable models and tools that could be used to translate evidence into practice.

VA HSR&D is focusing major resources and commitment to improve the quality of health care and create innovations that are measurable, rapid, and sustainable. Translation studies are funded by HSR&D via multiple mechanisms and cross a continuum from traditional health services research to rigorous evaluative quality improvement projects. HSR&D translation solicitations, including Service Directed Projects (SDP) and Investigator Initiated Research (IIR) solicitations designed to contribute to outcome and system-wide change, may be obtained from the following website: http://www.hsrd.research.va.gov/research/funding/solicitations/

VA's Quality Enhancement Research Initiative (QUERI) identifies gaps in evidence and practice, compares ideal to existing practice, translates evidence into outcome and system improvements, measures the impact of improvements, and actively promotes the use of the best available evidence by providers, policymakers, managers, patients, and others. With the inception of the QUERI in 1998, special emphasis has been placed on improvements in nine priority areas: congestive heart failure, ischemic heart disease, mental health, substance abuse, HIV/AIDS, stroke, diabetes, cancer, and spinal cord injury. The Cancer QUERI is a collaborative effort between VA HSR&D and the National Cancer Institute. Because QUERI and other VA HSR&D translation activities are comprehensive, data-driven, and outcomes based, performance measures and similar tools that promote linkages between research to practice are important. Additional information about QUERI is available on VA web page at http://www.hsrd.research.va.gov/about/queri/ and at http://www.turner-white.com/pdf/jcom_jan01_queri.pdf.

Objectives and Scope

The objective of this PA is to translate research evidence into practice and to inform decisionmaking at the clinical, organization/health care systems, and/or public policy levels, with an emphasis on the testing of effective and

efficient interventions that have the potential to improve clinical practice, enhance patient safety, and sustain practitioner behavior change across multiple health conditions, populations, and health care systems. Emphasis is placed on projects that introduce changes at the clinical, organization/health care systems, and/or public policy levels designed to facilitate rapid and widespread adoption of evidence in decisionmaking and/or implementation of evidence-based interventions into processes of care and then measure the impact of these efforts.

A special focus of this research is to identify: 1) if an implementation strategy that is successful with one clinical condition or patient population is equally successful with another clinical condition or population, particularly for patients in vulnerable populations and priority populations such as children, women, and the elderly; individuals with special healthcare needs, including persons with disabilities, those who need chronic care and end of life health care; individuals living in inner-city, rural, and frontier areas, and/or with comorbid conditions; 2) how the contextual factors of a site or organization contribute to a successful or unsuccessful translation effort; 3) how generalizable the results of any successful intervention are to other health care settings and sites, populations and clinical conditions; 4) the characteristics of interventions with high potential for sustainable improvements, and what factors enhance the likelihood of rapid and broad adoption; 5) the cost-effective strategies designed to put research evidence into practice; and 6) how a cost-effectiveness framework can be incorporated into decision-making within health care systems and/or at the public policy level.

Two categories of applications are eligible for consideration.

1) Comparative Studies: Studies conducted concurrently in VA and other settings.

For this category it is envisioned that a single study will include a component conducted in a VA setting and one or more components in a non-VA/private sector setting. Such a project could be led by one investigator with VA eligibility or by a research team that includes a VA-eligible investigator to serve as PI for the VA component. Studies in this category will consist of comparable methods, interventions, measures, and target populations. These studies will compare the effect of system, process, and other organizational factors on the use of evidence-based quality improvement intervention(s) within the VA health care system, to their simultaneous use in non-VA settings. If a Principal Investigator meets the eligibility criteria for both AHRQ and VA (see ELIGIBILITY REQUIREMENTS), then he/she may apply as a single PI for both VA site(s) and matched non-VA site(s). Two Principal Investigators, one with AHRQ eligibility and one with VA eligibility, may also collaborate and apply with matched projects to be operated by each PI at his/her respective site. Each proposal must have two corresponding research

components: one VA and one private-sector/non-VA (matched according to study design, methods, target audiences, and output). Approval will be needed from both VA and the private sector/non-VA Institutional Review Boards (IRB).

2) Translation Studies: Expanding the knowledge base for improvement. The second category of proposals includes the total range of translation studies called for in this PA. These studies may be done in either VA or non-VA settings. These studies may include: 1) the development and testing of study design, methods, or instruments relevant to the translation of evidence-based interventions into practice and the use of evidence to inform decisionmaking, and 2) the translation of existing evidence-based recommendations, tools, and/or strategies. The results of these efforts will be evaluated to determine their impact on clinical care (outcomes, processes, and/or structural effects), patient safety, or the health care system as a whole.

PA sponsors are especially interested in recommendations, tools, and strategies that can be used to implement research findings across multiple levels of health care delivery and multiple types of health care-related systems. The PA will support research that not only identifies and tests new methods for translating research into practice, but also expands the use of tested methods of translating evidence-based information across larger populations, different health care systems, or different clinical situations. Applications funded under this PA will translate research findings into practice via the dissemination, implementation, and evaluation of evidence-based recommendations, tools and strategies in diverse settings, populations, and payment systems. Levels of health care delivery include hospitals, nursing homes, ambulatory clinics, and homes where health care is provided. Health care systems of interest to AHRQ include purchaser groups, integrated health service delivery systems, academic health systems, managed care programs including HMOs, practice networks, worksite clinics, and safety net systems, e.g., community clinics.

PA sponsors are interested in interventions designed to improve clinical care, patient safety and clinical outcomes and strategies for sustaining improvements. These interventions may be targeted at the patient level, the health care provider level, the health care organizational delivery level, or the health care policy level. They may target specific types of health care providers or multiple disciplines. Evidence-based recommendations, tools, and/or strategies may be implemented at the local, State, regional or national levels for non-VA studies and at the local, Veterans Integrated System Network (VISN), or national level for VA studies. Interventions that address the needs of patients with one or more chronic illnesses and multiple types of care needs during an episode of illness are encouraged, although interventions using the evidence base to improve the clinical outcomes of patients with specific conditions, may also be designed. The use of information technology

as a critical component of effective translation strategies, as well as strategies for using cost-effectiveness analysis as a framework for improving health care delivery are also of interest.

Of particular interest are applications that test use of evidence-based recommendations, tools, and/or strategies derived from rigorously conducted research and measure the impact of translation. These may include but are not limited to findings from Patient Outcome Research Team (PORT) and QUERI efforts, United States Preventive Service Task Force recommendations, and evidence reports and technology assessments produced by the AHRQ Evidence-based Practice Centers.

The research applications sought under this PA should focus on applied research with the objective of developing sustainable and reproducible or generalizable strategies specifically designed to facilitate the use of evidence in decisionmaking and to implement existing research findings in order to change behavior, improve access, quality, or patient outcomes, including quality of life, and promote patient safety. Quantitative or qualitative research methods, including observational designs, may be used. The development and/or use of new and/or innovative methodologies designed to implement research findings and evaluate which existing methodologies have the most significant impact is a priority. Clinical, organizational, and system-level interventions, including State-focused or VISN-focused activities, may be tested and evaluated. Approaches to the wide-scale implementation of tested evidence-based approaches to improving quality of care should be considered. Of particular interest to AHRQ and VA are the use and evaluation of AHRQ or VA-sponsored research findings and products. Development of partnerships, such as those between researchers, professional organizations and health plans, to achieve improvement in outcomes is encouraged. In addition to studies focusing on cost-effectiveness models and methods used when translating research into practice, AHRQ, VA, and NIH are also interested in the translation of recommendations, tools, and strategies for the incorporation of a cost-effectiveness framework and cost-effectiveness studies focusing on decision-making within health care systems.

Partnerships

Relationships with public and private organizations to facilitate development and sharing of scientific knowledge and resources are encouraged. Partnerships or consortia, such as between academic and other research organizations and health plans, professional societies, consumer organizations and purchasers, can be formed to perform this research. Such partnerships may help to more quickly translate research findings into actual practice settings and help ensure that participating health care organizations sustain the intervention model as a continuing initiative beyond the end of the funded project. Roles of collaborators should be clearly defined in the application.

Racial and ethnic minority institutions are encouraged to apply for funding under this solicitation, and collaboration between minority and other institutions is also encouraged.

Research Methods

Because the impact on health outcomes of facilitating the use of evidence in decision making and translating evidence-based interventions may be difficult to measure directly within the desired time frame, focus on intermediate outcomes, process measures and resource use is appropriate. However, outcome and system links should be documented and the contribution of the proposed study results to ultimate outcome and system-wide improvements should be established. Studies that compare the cost and/or cost-effectiveness of implementation strategies as well as the development and use of cost-effectiveness analyses within health care systems to inform resource allocation and access to care are encouraged. Appropriate methods may include rigorous qualitative and quantitative measurement using observational or quasi-experimental designs. In order to monitor and account for secular changes in practice patterns, studies employing control or comparison groups are encouraged, but not required. The evaluation of interventions previously proven effective in one population, setting, or system are encouraged. Subgroup analyses to evaluate the impact of translation on subgroups, including vulnerable and priority populations such as indigent and rural populations, are strongly encouraged. All research designs and questions should be grounded in an appropriate theoretical framework that conceptually links existing evidence about the condition with evidence about the intervention used for translation. This theoretical framework needs to consider the strength of the evidence for the proposed intervention and clearly present why the investigator believes that the translation effort will result in measurable and sustainable improvements.

Research Priorities and Cross-Cutting Questions

Research Priorities

The overall objective of this PA is to identify ways to increase the successful application of interventions and practices that prior research has shown to be effective -- in other words to increase the rate and success of innovation diffusion for evidence-based practices. Our priorities cover two types of interventions. The first category involves clinical interventions, such as use of specific medications, technologies, evidence-based clinical practice guidelines and protocols, systematic reviews/evidence reports. The research questions for this PA then focus on implementation of these practices: what it takes for providers, patients, and clinical system leaders to learn about, adopt, and successfully implement these practices in order to

improve health care outcomes. The second category involves organizational, system or structural interventions: such as the use of dedicated AIDS units in hospitals, or open access scheduling. The research questions here also focus on implementation: what it takes for hospital or health plan leaders, or in some cases purchasers or policy-makers, to learn about, and successfully encourage or implement, these practices in order to improve quality and access and/or reduce cost. In other words, the first category focuses on increasing the practice of evidence-based clinical interventions, the second focuses on increasing the practice of evidence-based organizational and leadership interventions.

Clinical Evidence

A. Clinical Evidence: Targeting organizational or systems behavior to promote the implementation of clinical evidence

The focus of this priority is the dissemination, validation, replication, transfer or diffusion of organization or systems strategies for improved care. Strategies could include investments in information technology and decision support systems (for use by providers or patients), or other office-based systems. Examples of specific research questions include:

o For professional organizations that have been involved with implementation among their members, what methods have been utilized and what is the evidence of the interventions' effectiveness? What factors are associated with a professional organization's involvement in translation of research into practice activities? What skills and expertise are needed within a professional organization to be successful? What is the process by which a professional organization identifies an opportunity, and develops and implements an intervention?

o How does the structure of health care organizations affect implementation of evidence-based tools and information?

o What issues are unique to TRIP or QUERI efforts implemented across a range of clinical conditions (e.g., chronic illness) compared to a specific clinical condition? What strategies successfully facilitate such broad-reaching TRIP or QUERI efforts?

o What are effective approaches for implementing strategies incorporating cost-effectiveness considerations into decision-making within health care organizations?

o Is it feasible to develop and test predictive models of speed and effectiveness of adoption and diffusion of candidate clinical quality improvements that would provide guidance in considering TRIP and/or

QUERI efforts?

o What are the costs, benefits, and cost-effectiveness of TRIP or QUERI activities for an organization? What are specific financial barriers and potential strategies to minimize their impact?

o What is the effect of implementation of evidence-based tools and information on health care organizations in terms of resource use and cost?

B. Clinical Evidence: Targeting provider behavior to promote the implementation of clinical evidence

The focus of this priority is the dissemination, validation, replication, transfer or diffusion of known effective strategies for improved care through changes in provider behavior. All types of clinical providers are encompassed in this category. Examples of specific questions include:

o Are there underlying similarities/differences across dissemination efforts that predict success/failure? Can a model be developed to accurately reflect them?

o What characteristics of continuing education appear to be related to behavior change?

o Which methods are most effective, cost-effective, and/or sustainable in assisting providers to stay abreast of the most recent scientific evidence in their areas of clinical specialization?

o Which factors motivate them, or serve as barriers, to their use of that evidence in their clinical decisionmaking?

o What role can professional licensure, accreditation, and continuing education activities play in effectively using current scientific evidence to maintain and enhance clinical performance?

o How can one motivate and sustain changes in provider behavior necessary for evidence-based practice (taking into account differences, if any, related to areas of specialization and the stages in a clinician=s career, e.g., student, resident, mid-career, etc.)?

o How can continuing education interventions be modified or augmented to increase their impact on behavior change?

o Are there inter-disciplinary differences in adopting or sustaining use of new evidence and/or changing behavior

o What strategy or combination of strategies consistently stimulates improved behavior change?

o How have the trends towards Continuous Professional Development and board certification affected outcomes or processes of care?

C. Clinical Evidence: Targeting patient behavior to promote the implementation of clinical evidence

The focus of this priority is the dissemination, validation, replication, transfer or diffusion of known effective strategies that support the role of patients (and their families, friends, or caregivers) in translating research into practice. Examples of specific research questions include:

o How can patients obtain and understand reliable information regarding their medical condition and alternative treatment options and effectively use that information to enhance the quality and outcomes of care they receive?

o What are the effects of evidence-based clinical information on patient safety and patient/consumer quality of life, satisfaction with care, behavior, knowledge, and attitudes?

o How can patients make effective use of their discussions with clinicians and other caregivers and participate (to the extent they are comfortable) in decisionmaking regarding their course of treatment?

o How can patients be brought into partnership with health care providers and health care organizations in creating and sustaining change?

o How do different implementation strategies affect patient satisfaction? For example, is patient activation a more useful tool for those patients with Internet access than for those without?

o How can new information technology applications (e.g., the Internet, etc.) be used to effectively enhance patient understanding and use of research in their care-seeking behavior?

Organizational Evidence: Expanding Evidence-based Management and Leadership

A second priority for this PA focuses on the dissemination, validation, replication, transfer or diffusion of evidence regarding organizational or systems interventions which have been shown to work in at least some settings to improve the quality, outcomes, access or cost of care. Two recent reports of the Institute of Medicine (1999, 2001) point to major problems in health care safety, effectiveness, patient centeredness, timeliness, efficiency, and equity. Both reports identify poor systems as major causes of these problems,

and state explicitly that "if we want safer, higher-quality care, we will need to have redesigned systems of care " (IOM 2001).

Some of the evidence base for improving systems of care exists already. AHRQ has been the primary sponsor for organizational design research in the past. Research projects under a 1997 RFA, "Quality of Care under Varying Features of Managed Care Organizations" are in their final stages and AHRQ recently announced a new Program Announcement "Impact of Payment and Organization on Cost, Quality, and Equity,"
(See http://grants.nih.gov/grants/guide/pa-files/PA-01-125.html) that should add to this evidence base. For example, past research has shown that, in at least some settings:

o Reorganization of practices (use of multidisciplinary teams, careful allocation of tasks among team members, and ongoing management of patient contacts) can improve outcomes for chronically ill patients (Wagner et al., 1996, cited in IOM 2001).

o Increasing RN hours per patient can decrease the incidence of urinary tract infection, pneumonia, thrombosis, and pulmonary compromise (Kovner et al. 1998).

o Use of hospital dedicated AIDS units can bring higher patient satisfaction, lower nurse burnout, and lower odds of dying within 30 days of admission.

o Use of open access scheduling yields more effective, patient-centered, timely, and efficient care (Institute for Healthcare Improvement 2000, cited in IOM 2001).

But the next challenge for evidence-based management, as for evidence-based medicine, is to identify ways to increase the adoption and use of the evidence that exists already. According to one recent review of evidence-based management practices (Kovner, Elton and Billings 2000 p. 4) managers in large healthcare organizations are deciding on more and riskier strategic interventions based on evidence that is not systematically gathered or assessed. The second priority for this PA, therefore, is to identify and test strategies for increasing the successful adoption and implementation of proven organizational interventions.

Organizational interventions can occur with different foci -- technological improvement, service enhancement, administrative/structural change, and personnel development. In many instances, a combination of these interventions is required to effectively achieve the desired improvement. These interventions can take place incrementally and some types of changes might be easier to implement than others. More research is needed to

establish evidence for the effectiveness of different organizational interventions and successful implementation strategies.

Decisions related to organizational interventions also occur at multiple levels. The decision to begin a care coordination program for chronically ill patients, for example, might be made by a medical group, the health care delivery system to which it belongs, or the health plan that contracts with the system. (See Landon, Wilson and Cleary 1998). Moving up the chain, the decision might also be made or influenced by the public or private payer (the Medicaid program, or a large employer). In the case of broad organizational decisions (the use of Primary Care Case Management for enrollees, for example) the decision may even be made or at least influenced by Federal, State or local policy-makers or managers.

For any of these types of organizational interventions, or levels of decision-makers, we would be interested in three broad issues:

A. Organizational Evidence: Replication.

If the organizational intervention works in site A, does it work in site B? If so, what change in the implementation strategy does it take to make it work (for example, a VA site versus a non-VA site, or hospitals versus outpatient settings)?

B. Organizational Evidence: Applicability and/or adaptation for priority populations.

If the organizational intervention works for serving population A, does it work for serving population B, and in particular priority populations? If so, what change in the implementation strategy does it need to make it work (for example, Caucasian versus African-American, or adults versus children)?

C. Organizational Evidence: Innovation diffusion and implementation

What does it take for managers and health care leaders of all types of organizations to increase their knowledge and take-up of this intervention? What does it take for other actors with a major impact on these systems (e.g., public and private purchasers, public policy-makers) to increase their knowledge and take-up of this intervention?

- What dissemination strategies are most effective for reaching them?

- How must translation and dissemination strategies vary from one type of decision-maker (e.g., board members, chief executive officers, chief information officers, chief financial officers, clinical managers, government policy makers) to another?

o How must translation and dissemination strategies vary from one type of organization (e.g., hospitals, home health agencies, long-term care facilities, managed care organizations, insurers, purchasers, state government, local government, etc.) to another?

o How do different types of decision-makers differ from researchers in the sorts of "evidence" they find sufficient for action?

o What does it take for health care managers and health care leaders to implement these strategies successfully?

o What kind of tools and technical support do they need?

Cross-Cutting Questions

o How sustainable are improvements that result from various interventions over time? For example, are improvements resulting from use of audit and feedback longer-lasting than those resulting from use of opinion leaders? To what extent are these differences stable across conditions?

o What are the ethical implications of studies comparing an implementation strategy with usual practices? Are there standards for comparison groups? How will these implications influence investigator incentives?

o What are effective approaches that apply multifaceted strategies to implementation of evidence-based tools and information?

o What are strategies for identifying, validating, and addressing barriers to implementation of evidence-based tools and cost-effectiveness information?

o Is there a measurable difference in the effectiveness of evidence-based tools and information depending on the match of the race/ethnicity of providers and patients?

o Is the identification of sub-populations meaningful in identifying the effectiveness of evidence-based tools and information? Is culture a more valid variable than race/ethnicity?

Methods: Use and Evaluation

o Using meta-analytic or systematic review methods, what can one infer from the literature on implementation of quality improvement interventions, rankings of the effectiveness of different TRIP and/or QUERI interventions, alone or in combination?

o What are the best methods for studying natural experiments such as introduction of legislation mandating new coverage policies?

o What is the comparative cost-effectiveness of various strategies for implementing evidence-based tools and information?

MECHANISM OF SUPPORT

This PA will use the R01 award mechanism for applicants applying for AHRQ. As an applicant, you will be solely responsible for planning, directing, and executing the proposed project.

Applicants are encouraged to contact the Agency listed under WHERE TO SEND INQUIRIES that matches their research interest, and to seek guidance on other potential grant mechanisms that are applicable to each Agency. The total project period for an application submitted in response to this PA may not exceed five years.

AHRQ is not using the Modular Grant Application and Award Process.

Applicants interested in applying to AHRQ for a small research grant (projects requesting total cost of $100,000 or less) (RO3) should consult the program contact. Procedures are outlined in the "AHRQ Small Research Grant Program" PA, published in the NIH Guide for Grants and Contracts (NIH Guide) January 2, 2001.

ELIGIBLE INSTITUTIONS

You may submit (an) application (s) if your institution has the following characteristics:

1. Eligible to AHRQ

o Public and private non-profit institutions such as universities and clinics
o Units of State and local governments
o Eligible agencies of the Federal government
o Domestic and foreign
o Faith-based organizations

Note: AHRQ, by statute, can make grants only to not-for-profit organizations; however, for profit organizations may participate in grant projects as members of consortia or as subcontractors. Organizations described in section 501(c) 4 of the Internal Revenue Code that engage in lobbying are not eligible.

2. Eligible to VA HSR&D

o PIs and co-PIs must hold a minimum 5/8ths VA paid appointment
o Non-PI investigators who collaborate on the project do not need to hold a VA appointment

Note: Further questions about eligibility to be a VA investigator may be referred to the VA HSR&D Eligibility Coordinator, Ms. Caryn Cohen, at 202-273-6812 or caryn.cohen@hq.med.va.gov. You may also refer to the policy Eligibility For VA Research Support available on the VHA R&D web site at http://www.va.gov/publ/direc/health/direct/195036.htm or in the following online handbook:
http://www.va.gov/resdev/directive/VHA_Handbook_1200.15_Eligibility.doc.

INDIVIDUALS ELIGIBLE TO BECOME PRINCIPAL INVESTIGATORS

Any individual with the skills, knowledge, and resources, necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for grant support.

SPECIAL REQUIREMENTS

Policy Relevance and Dissemination

Applications submitted in response to this PA are expected (1) to contribute to our basic understanding of how to effectively and efficiently translate research evidence into practice leading to measurable and sustained improvement, (2) to build capacity - research tools, data, and teams B in order to answer related policy relevant questions, and (3) to produce information in formats useful to participants in the formulation of clinical and public policy. Applicants should be concrete in describing relevant policy implications in terms of (1) the decision-making audiences most interested in the proposed research (2) how applicants anticipate their results being used and by what audiences and (3) the presence or absence (gap) of strong evidence that influences policy development.

Dissemination strategies should not be limited to publication in peer-reviewed journals but may encompass a variety of active approaches, such as translating results into non-technical monographs and distributing them through associations of private and public officials; educating legislators, public administrators, health plan executives, employers, health professionals, and others in seminars; and outreach to mass media. Plans, time lines, personnel, and budgets for such dissemination efforts should be explicitly presented.

Publications Transmittal: General AHRQ Requirements

In keeping with the Agency=s efforts to translate the results of AHRQ-funded research into practice and policy, grantees and/or contractors are to inform the Office of Health Care Information (OHCI) when articles from their studies are accepted for publication in the professional literature. Grantees and contractors should also discuss any ideas about other dissemination and marketing efforts with OHCI staff. The goal is to ensure that efforts to disseminate research findings are coordinated with other Agency activities to maximize awareness and application of the research by potential users, including clinicians, patients, health care systems and purchasers and policymakers. This is critical when outreach to the general and trade press is involved. Contact with the media will take place in close coordination with OHCI and the press offices of the grantee=s or contractor=s institutions. In cases when products are created (such as annual or final reports, Web-based tools, CD-ROMs), grantees and contractors will be asked to submit to OHCI a brief plan describing how the product will be publicized. An OHCI staff person will be assigned to each product and will coordinate the implementation of the plan, especially issues related to printing and electronic dissemination, and outreach to the media.

Publications Transmittal: General VA Requirements

Investigators are required to send VA HSR&D a copy of each article resulting from VA HSR&D- funded research as soon as it is accepted for publication. Submit each article by e-mail to: vhacohsrd@mail.va.gov. For additional information and details regarding investigators= responsibilities related to publications resulting from VA-supported research, please consult your local R&D office and refer to the following website: http://www.va.gov/resdev/fr/manualm3.cfm.

WHERE TO SEND INQUIRIES

We encourage your inquiries concerning this PA and welcome the opportunity to answer questions from potential applicants who have read the PA. Inquiries may fall into three areas: scientific/research, peer review, and financial or grants management issues:

1. AHRQ

o Direct your questions regarding AHRQ programmatic issues including information on the inclusion of women, minorities, and children in study populations to:

Clinical Interventions

Margaret Coopey, RN, MGA, MPS/ Diane Brown
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Organizational Interventions

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2101 East Jefferson Street, Suite 605
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2. VA

o Direct your questions about VA/QUERI programmatic issues to:

Lynn McQueen, DrPH, MS, RN
Associate Director for HSR&D, QUERI (124Q)
HSR&D, VA Central Office
810 Vermont Avenue, NW
Washington, DC 20420
Phone: (202) 273-8227
Fax: (202) 273-9007
E-mail: lynn.mcqueen@hq.med.va.gov

VA eligibility matters

Caryn Cohen, MS
Health Science Specialist & Eligibility Coordinator (124I)
HSR&D, VA Central Office
810 Vermont Avenue, NW
Washington, DC 20420
Phone: (202) 273-6812
Fax: (202) 273-9007
E-mail: caryn.cohen@hq.med.va.gov

Mental health research at the VA

Richard Owen Jr., MD

Director, HSR&D Center for Mental Healthcare and Outcomes Research, (152/NLR)
Central Arkansas Veteran Healthcare System
2200 Ft. Roots Drive
North Little Rock, AR 72114
Phone: (501) 257-1710
FAX: (501) 257-1707
FTS: (700) 740-1622
E-mail: owenrichardr@uams.edu

3. NIH

o Direct your questions to NIMH that focus on the translation of research evidence in the area of mental health to:

David Chambers, Ph.D.
Dissemination Research Program
Division of Services and Intervention Research
National Institute of Mental Health
6001 Executive Blvd., Rm. 7133, MSC 9631
Bethesda, MD 20892-9631
Telephone: (301) 443-3364
FAX: (301) 443-4045
E-mail: dchamber@.mail.nih.gov

o Direct your questions to NCI that focus on the translation of research evidence in the area of cancer care services to:

Molla Sloane Donaldson, Dr. P.H.
Outcomes Research Branch, ARP, DCCPS
National Cancer Institute
6130 Executive Blvd., MSC 7344
EPN Room 4028
Bethesda, MD 20892-9631
for overnight delivery use: Rockville, MD 20852
Telephone: (301) 435-1638
FAX: (301) 435-3710
Donaldsm@mail.nih.gov

o Direct your questions to NIAAA about Alcohol Abuse and Alcoholism to:

Mike Hilton, Ph.D.
Division of Clinical and Prevention Research
National Institute on Alcohol Abuse and Alcoholism
Willco Building, Suite 505
6000 Executive Blvd., MSC 7003
Bethesda, MD 20892-7003

Telephone: 301-443-8753
FAX: 301-443-8774
Email: mhilton@willco.niaaa.nih.gov

o Direct your questions about peer review issues to:

Joan Hurley, SRA
ORREP
Agency for Healthcare Research and Quality
2101 E. Jefferson Street, Rm. 4W3
Rockville, MD 20852
Telephone: (301) 594-6075
Fax: (301) 594-2329
Email: jhurley@ahrq.gov

A. AHRQ

o Direct your questions about AHRQ financial or grants management matters to:

George Gardner
Grants Management Specialist
Agency for Healthcare Research and Quality
2101 East Jefferson Street, Suite 601
Rockville, MD 20852
Telephone: (301) 594-6826
FAX: (301) 594-3210
Email: ggardner@ahrq.gov

B. VA

Direct your questions about VA fiscal matters to:

Teresa Mathis, CRA, MBA
Program Analyst, Operations (124G)
HSR&D, VA Central Office
810 Vermont Avenue, NW
Washington, DC 20420
Phone: (202) 273-8860
Fax: (202) 273-9007
E-mail: teresa.mathis@hq.med.va.gov

SUBMITTING AN APPLICATION

Applications must be prepared using the PHS 398 research grant application instructions and forms (rev. 5/2001). The PHS 398 is available at http://grants.nih.gov/grants/funding/phs398/phs398.html in an interactive

format. For further assistance contact GrrantsInfo, Telephone (301) 435-0714, Email: GrantsInfo@nih.gov.

State and local government applicants may use PHS 5161-1, Application for Federal Assistance (rev. 5/96), and follow those requirements for copy submission. Applicants are encouraged to read all PHS Form 398 instructions prior to preparing an application in response to this PA.

Copies of the PA are available from:

AHRQ Publications Clearinghouse
P.O. Box 8547
Silver Spring, MD 20907-8547
Telephone: 1-800-358-9295
TDD Service: 888-586-6340

The PA is also available on AHRQ's web site, http://www.AHRQ.gov (Funding Opportunities), and through AHRQ InstantFAX at (301) 594-2800. To use InstantFAX, you must call from a facsimile (FAX) machine with a telephone handset. Follow the voice prompt to obtain a copy of the table of contents, which has the document order number (not the same as the PA number). The PA will be sent at the end of the ordering process. AHRQ InstantFAX operates 24 hours a day, 7 days a week. For comments or problems concerning AHRQ InstantFax, please call (301) 594-6344.

This PA is also available at the following VA website: http://www.va.gov/resdev/fr/frrfp/solicitations.cfm.

SPECIAL APPLICATION PROCEDURES:

1. VA

Projects funded by VA will use VA's Investigator Initiated Research (IIR) mechanism. All investigators who meet VA eligibility criteria and wish to be considered for VA funding will be required to fill out and submit specific VA budget forms as an appendix of the application. The required forms must be included with the PHS form 398 and include: VA Forms 10-1313-3 and 10-1313-4 addressing the First Year Request and Budget Justification (see http://www.va.gov/resdev/fr/forms.cfm website to obtain these forms). All research to be completed at a VA facility requires local Research &Development (R&D) Committee and Associate Chief of Staff for Research approval at time of submission. Studies involving human subjects must be accompanied by the consent form. VA Form 10B1086, Agreement to Participate in Research By or Under the Direction of VA, that will be presented to each subject or legally responsible representative prior to the subject=s participation in the study.
A completed and current VA Form 10-1223, Report of Subcommittee on Human

Studies, dated no earlier than one year before the receipt date of the application, may be submitted with the application, but must be received prior to release of any VA funding. Questions about VA forms may be directed to any VA medical facility's Office of Associate Chief of Staff for Research and Development or to Ms. Becky Kellen at 202-273-8260 or becky.kellen@hq.med.va.gov.

2. AHRQ

Beginning with applications for AHRQ funding submitted for the February 1, 2001 receipt date, Institutional Review Board (IRB) approval of human subjects is not required prior to peer review of an application unless otherwise indicated by the Agency (http://grants.nih.gov/grants/guide/notice-files/NOT-HS-00-003.html). All investigators/applicants proposing research involving human subjects should pay particular attention to the instructions in the form PHS 398 regarding human subject involvement.

Application Preparation (for Using Center for Medicare and Medicaid Services (CMS) Data)

For applications that propose to use Medicare or Medicaid data that are individually identifiable, applicants should state explicitly in the "Research Design and Methods" section of the Research Plan (form PHS 398) the specific files, time periods, and cohorts proposed for the research. In consultation with Centers for Medicare and Medicaid Services (CMS), formerly Health Care Financing Administration (HCFA), AHRQ will use this information to develop a cost estimate for obtaining the data. This estimate will be included in the estimated total cost of the award at the time funding decisions are made. To avoid double counting, applicants should not include the cost of the data in the budget.

Applicants should be aware that for individually identifiable Medicare and Medicaid data, Principal Investigators and their awardee institutions will be required to enter into a Data Use Agreement (DUA) with CMS to protect the confidentiality of data in accordance with OMB Circular A-130, Appendix III--Security of Federal Automated Information Systems. The use of the data is restricted to the purposes and time period specified in the DUA. At the end of this time period, the awardee is required to return the data to CMS or certify that the data have been destroyed.

For the sole purpose of assuring that data confidentiality is maintained, included in the DUA is the requirement that the User agrees to submit to CMS a copy of all findings within 30 days of making such findings. The user agrees not to submit these findings to any third party (including but not limited to any manuscript to be submitted for publication) until receiving CMS's approval to do so.

Awardees must also comply with the confidentiality requirements of Section 924 (c) of the PHS Act (42 U.S.C. 299c-3(c). See the Data Privacy section for details on these requirements as well as references to Circular A-130 and its implementation guides for the National Institute of Standards and Technology.

In developing research plans, applicants should allow time for refining and processing their data requests. Approval may take six months from the date submitted to complete. Applications proposing to contact beneficiaries or their providers require the approval of the CMS administration and may require meeting(s) with CMS staff.

CMS data are provided on IBM mainframe tapes using the record and data formats commonly employed on these computers. Applicants should either have the capability to process these tapes and formats or plan to make arrangements to securely convert them to other media and formats.

Questions regarding CMS data should be directed to the AHRQ program official listed under INQUIRIES.

In carrying out its stewardship of health care related programs, the AHRQ will request information essential to an assessment of the effectiveness of Agency research programs. Accordingly, award recipients are hereby notified that they may be contacted after the completion of awards for periodic updates on publications resulting from AHRQ grant awards, and other information helpful in evaluating the impact of sponsored research.

To receive an award, applicants must agree to submit an original and 2 copies of an abstract, executive summary, and full report of the research results in the format prescribed by AHRQ no later than 90 days after the end of the project period. The executive summary should be sent at the same time on a computer disk which specifies on the label the format used (WP5.1 or WP6.0 is preferable).

APPLICATION RECEIPT DATES: Applications submitted in response to this program announcement will be accepted at the standard application deadlines, which are available at http://www.ahrq.gov (Funding Opportunities).

SPECIFIC INSTRUCTIONS FOR MODULAR GRANTS APPLICATIONS:

1. AHRQ

AHRQ is not using the modular grant application and award process. Applicant for funding from AHRQ should ignore application instructions concerning the modular grant application and award process, and prepare applications according to instructions provided in form 398. Applications submitted in the

modular format will be returned without review.

BUDGET INSTRUCTIONS:

AHRQ

AHRQ uses the detailed budget for research grant applications. Applicants for funding from AHRQ should use PHS form page 4 and form page 5 and follow the instructions for detailed budget for initial budget period, page 10.

SPECIFIC INSTRUCTIONS FOR APPLICATIONS REQUESTING $500,000 OR MORE PER YEAR:

For AHRQ

Note that proposed projects with direct costs exceeding $500,000 in any one year require permission from AHRQ program staff two months prior to submission of the application.

CENTER FOR SCIENTIFIC REVIEW
NATIONAL INSTITUTES OF HEALTH
6701 ROCKLEDGE DRIVE, ROOM 1040, MSC 7710
BETHESDA, MD 20892-7710
BETHESDA, MD 20817 (for express/courier service)

APPLICATION PROCESSING: Applications must be received by or mailed before the receipt dates described at http://grants.nih.gov/grants/funding/submissionschedule.htm. The CSR will not accept any application in response to this PA that is essentially the same as one currently pending initial review unless the applicant withdraws the pending application. The CSR will not accept any application that is essentially the same as one revision of an application already reviewed, but such application must include an Introduction addressing the previous critique.

On line 2 of the face page of the application, mark the yes box and type the PA number and title in the space provided.

The PHS 398 type size requirements (p.6) will be enforced rigorously and non-compliant applications will be returned.

PEER REVIEW PROCESS

1. For AHRQ & VA Applications

Applications submitted for this PA will be assigned on the basis of

established PHS referral guidelines. An appropriate scientific review group comprise of both AHRQ and VA-selected reviewers and convened in accordance with AHRQ peer review procedures will evaluate applications for scientific and technical merit. Application peer review will be administered by AHRQ with AHRQ and VA collaboration on content, review, and funding decisions.

As part of the initial merit review, all applications will:
o Receive a written critique
o Undergo a process in which only those applications deemed to have high scientific merit will be discussed and assigned a priority score

The peer reviewers will be asked to judge the likelihood that the proposed projects will have a substantial impact on the pursuit of the goals specified in this PA and will also be evaluated regarding the appropriateness of proposed project budget and duration; the adequacy of plans to include both genders and minorities and their subgroups as appropriate for the scientific goals of the research and plans for the recruitment and retention of subjects; the provisions for the protection of human subjects; and the safety of the research environment.

Each of the following criteria will be addressed and considered by the reviewers in assigning the overall score, weighting them as appropriate for each application. Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus attain a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward. General review criteria include:

A. SIGNIFICANCE: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will the effect of these studies be on the concepts or methods driving this field?

B. APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well integrated, and appropriate to the aims of the project? Are the proposed data sources appropriate and adequate? Does the applicant acknowledge potential problem areas and consider alternative tactics?

C. INNOVATION: Does the project employ innovative information technology applications, concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or test methodologies or technologies? Once completed, will the findings contribute new and generalizable knowledge?

D. INVESTIGATOR: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience

level of the principal investigator and other researchers? Is the project (or work plan) well organized? Does the proposed study team reflect the multi-disciplinary approach required to address the project=s research issues?

E. ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

F. POLICY RELEVANCE: Will the project provide Federal and State policymakers, and others participating in the formulation of such policy, with the evidence-based information they need to improve quality and/or patient safety? Does the application provide a sound plan for achieving this purpose?

The scientific review group will also examine issues specifically relevant to translation, including issues relevant to proposed dissemination, implementation, and evaluation activities. Review criteria relevant to translation include:

a) The extent that a cogent theoretical framework that unites evidence about the condition with evidence about translation is used; strength of evidence is considered and reason to believe that the intervention will result in a measurable improvement is described.

b) The extent that clear definitions of key terms, including "usual care", are provided and used consistently especially in text related to any control and/or comparison groups.

c) The extent to which the study results will be applicable and generalizable to situations beyond that of the study and contribute to improved translation of research evidence across a range of settings, levels of care, and populations.

d) The extent to which the translation project will result in sustainable improvements in the adoption of research findings into practice.

INCLUSION: The adequacy of plans to include subjects from both genders, all racial and ethnic groups (and subgroups), and children as appropriate for the scientific goals of the research. Plans for the recruitment and retention of subjects will also be evaluated. (See Inclusion Criteria included in the section on Federal Citations, below)

DATA SHARING:

Data Privacy: AHRQ and VA Requirements

Pursuant to section 924(c) of the Public Health Service Act (42 USC 299c-3(c)), information obtained in the course of any AHRQ-study that identifies an individual or entity must be treated as confidential in accordance with any explicit or implicit promises made or implied regarding the possible uses and disclosures of such data. In the Human Subjects section of the application, applicants must describe procedures for ensuring the confidentiality of the identifying information to be collected. The description of the procedures should include a discussion of who will be permitted access to the information, both raw data and machine-readable files, and how personal identifiers and other identifying or identifiable data will be restricted and safeguarded.

The awardee should ensure that computer systems containing confidential data have a level and scope of security that equals or exceeds those established by the Office of Management and Budget (OMB) in OMB Circular No. A-130, Appendix III - Security of Federal Automated Information Systems. The National Institute of Standards and Technology (NIST) has published several implementation guides for this circular. They are: An Introduction to Computer Security: The NIST Handbook; Generally Accepted Principals and Practices for Securing Information Technology Systems; and Guide for Developing Security Plans for Information Technology Systems. The circular and guides are available on the web at http://csrc.nist.gov/publications/nistpubs/800-12/handbook.pdf. The application of these confidentiality and security standards to subcontractors and vendors should be addressed as necessary.

VA has the following additional requirement for Privacy of Information. All applications must include a letter from the facility Privacy Officer (usually the Chief, Medical Administration Service) identifying the PI's name and project title and providing evidence of due regard for the Privacy Act of 1974 (Public Law 93-579) and intent by the PI to comply. The statement should be signed, dated and the signator identified by name, title, and affiliation. Privacy Act is not applicable to grants records but to VA facility records. After April 2003, patient record information must be maintained in accordance with any agreements made with health care providers pursuant to the HHS Privacy Regulation 45 CFR Parts 100 and 164.

Rights in Data: AHRQ Requirements

AHRQ grantees may copyright or seek patents, as appropriate, for final and interim products and materials including, but not limited to, methodological tools, measures, software with documentation, literature searches, and analyses, which are developed in whole or in part with AHRQ funds. Such copyrights and patents are subject to a worldwide irrevocable Federal government license to use and permit others to use these products and materials for government purposes. In accordance with its legislative

dissemination mandate, AHRQ purposes may include, subject to statutory confidentiality protections, making research materials, data bases, results, and algorithms available for verification or replication by other researchers; and subject to AHRQ budget constraints, final products may be made available to the health care community and the public by AHRQ or its agents, if such distribution would significantly increase access to a product and thereby produce public health benefits. Ordinarily, to accomplish distribution, AHRQ publicizes research findings but relies on grantees to publish research results in peer-reviewed journals and to market grant-supported products.

Important legal rights and requirements applicable to AHRQ grantees are set out or referenced in the AHRQ's grants regulation at 42 CFR Part 67, Subpart A (Available in libraries and from the GPO's website http://www.access.gpo.gov/nara/cfr/index.html).

All VA investigators affiliated with the project must be aware of and follow VA policies regarding VA support acknowledgment. Specifically, all publications and presentations based on research supported by VA must acknowledge VA support, and the investigator's VA affiliation must appear, before any other (see exception below), in the following form: "The research reported here was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service (project no.). Dr. XXX is the (position title) at (location)." In addition, all publications should include a disclaimer similar to this statement: "The views expressed in this article are those of the author(s) and do not necessarily represent the views of the Department of Veterans Affairs."

AWARD CRITERIA

Two distinct categories of applications are requested under this PA. The first category of applications (dual/twin projects where comparisons are made by implementing the same study inside and outside VA) will be jointly funded by VA and AHRQ. AHRQ will fund the private sector/non-VA site(s) and VA will fund studies implemented in VA site(s) unless the PI has less than a 5/8th appointment. The second category of applications (general translation/non comparison studies of VA and private sector sites) will be funded by AHRQ or VA. VA studies will be funded by either VA or AHRQ and private sector/non-VA studies will be funded by AHRQ.

Applications will compete for available funds with other investigator-initiated applications requesting support. Final award decisions regarding VA funding will be made by the Director, VA HSR&D. Final decisions about AHRQ funding will be made by the Director of AHRQ. The following will be considered in making funding decisions: quality of the proposed project as determined by peer review and how well it fits the funding agency=s priorities, program balance, and availability of funds.

REQUIRE FEDERAL CITATIONS

A. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS: It is the policy of AHRQ and VA that women and members of minority groups be included in all AHRQ and VA research projects involving human subjects, unless a clear and compelling rationale and justification are provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The AHRQ policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 101-43). However, the subject population of VA research should reflect the demographics of the veteran population and the constraints of VA population are recognized, as described in VHA Handbook 1200.9, "Inclusion of Women and Minorities in Research" http://www.va.gov/resdev/directive/Women_and_minorities.doc.

Specific AHRQ

All investigators proposing research involving human subjects should read the UPDATED "NIH Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research" published in the NIH Guide for Grants and Contracts on August 2, 2000. (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-048.html). A complete copy of the updated Guidelines is available at http://grants.nih.gov/grants/funding/women_min/guidelines_update.htm. The revisions relate to NIH defined Phase III clinical trials and require: a) all applications or proposals and /or protocols to provide a description of plans to conduct analyses, as appropriate, to address differences by sex/gender and/or racial/ethic groups, including subgroups if applicable; and b) all investigators to report accrual, and to conduct and report analyses, as appropriate, by sex/gender and/or racial/ethnic group differences. To the extent possible, AHRQ requires adherence to these NIH guidelines.

Investigators may obtain copies from the above sources or from the AHRQ Publications Clearinghouse, listed under INQUIRIES.

B. INCLUSION OF CHILDREN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS:

AHRQ encourages investigators to consider including children in study populations, as appropriate.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" that was published in the NIH Guide for Grants and Contracts, March 6, 1998, and is available at the following URL address: http://grants.nih.gov/grants/guide/notice-files/not98-024.html.

Investigators also may obtain copies of these policies from the program staff listed under INQUIRIES. Program staff may also provide additional relevant information concerning the policy.

Specific VA Requirements

Considering the constraints of VA patient population, applicants for VHA research support are expected to include women and minorities in their study populations. Special efforts shall be made to include women and minority groups in studies of diseases, disorders, and conditions that affect them. All investigators proposing research involving human subjects and who are seeking VA funding should read VHA Handbook 1200.9, "Inclusion of Women and Minorities in Research" found at the following website, http://www.va.gov/resdev/directive/Women_and_minorities.doc. VA restrictions regarding research on children are explained in the following directive: VHA Directive 2001-028, "Research Involving Children" (http://www.va.gov/publ/direc/health/direct/12001028.pdf).

C. PUBLIC ACCESS TO RESEARCH DATA THROUGH THE FREEDOM OF INFORMAITON ACT: For AHRQ) The Office of Management and Budget (OMB) Circular A-110 has been revised to provide public access to research data through the Freedom of Information Act (FOIA) under some circumstances. Data that are (1) first produced in a project that is supported in whole or in part with Federal funds and (2) cited publicly and officially by a Federal agency in support of an action that has the force and effect of law (i.e., a regulation) may be accessed through FOIA. It is important for applicants to understand the basic scope of this amendment. It is not likely that data gathered under projects supported through this initiative will be used as a basis for federal regulation or action having the force and effect of law. However, should applicants wish to place data collected under this PA in a public archive, which can provide protections for the data (e.g., as required by the confidentiality statute applicable to AHRQ supported projects, 42 U.S.C. 299c-3c) and manage the distribution of non-identifiable data for an indefinite period of time, they may. The application should include a description of any archiving plan in the study design and include information about this in the budget justification section of the application. In addition, applicants should think about how to structure informed consent statements and other human subjects procedures given the potential for wider use of data collected under this award.

D. HEALTHY PEOPLE 2010: The Public Health Service (PHS) is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2010," a PHS-led national activity for setting health improvement priorities for the United States. AHRQ encourages applicants to submit applications with relevance to the specific objectives of this initiative.

Potential applicants may obtain a copy of "Healthy People 2010" at http://www.health.gov/healthypeople.

E. AUTHORITY AND REGULATIONS: For AHRQ, this program is described in the Catalog of Federal Domestic Assistance, Number 93.226. Awards are made under authorities in Title IX of the Public Health Service Act (42 USC 299-299c-7) as amended by P.L. 106-129 (1999). AHRQ awards are administered under the PHS Grants Policy Statement and Federal Regulations 42 CFR 67, Subpart A, and 45 CFR Parts 74 or 92. This program is not subject to the intergovernmental review requirements of Executive Order 12372 or Health Systems Agency review.

All VA support will be subject to all applicable VA and Federal guidelines and regulations governing expenditures of VA funds.

The PHS strongly encourages all grant and contact recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some case, any portion of a facility) in which regular or routine education, library, day care, health care or early childhood development services are provided to children. This is consistent with the PHS mission to protect and advance the physical and mental health of the American people.

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